

REMARKS

Reconsideration of the application is respectfully requested.

I. Status of the Claims

Claims 4 - 7 were previously cancelled, without prejudice or disclaimer of the subject matter contained therein.

Claim 9 was found by the Examiner as being drawn to an unelected invention as defined by a previous restriction requirement, and was previously withdrawn.

Claims 1 and 8 are herein amended. No new matter is added.

Claims 1 - 3, 8, and 9 are pending and stand rejected.

II. Specification

The Examiner objects to the specification as failing to provide proper antecedent basis for the claimed subject matter. Applicants respectfully traverse the Examiner's assertion that the specification does not teach which of the variables and equations disclosed on pages 12-30 of the specification corresponds in Claim 8 to the claimed second measurement value, the second theoretical value, the difference between the second measurement value and the second theoretical value, the adjusted blood flow rate, and the second predetermined acceptable ration difference. Support for all of the above can be found in the specification as filed at page 33, lines 1-16, and at page 34, line 19 to page 35, line 4.

III. Claim Objections

Claims 1-3 and 8 are amended and now avoid the Examiner's objections to informalities.

IV. Rejections under 35 U.S.C. § 112

Claims 1-3 and 8 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner asserts that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In claim 1, the theoretical ratio value relationship Q_{uf}/Q_b was inadvertently reversed. Claim 1 is amended to overcome the rejection and Applicants thank the Examiner for bringing this to Applicants' attention.

V. Rejections under 35 U.S.C. § 103

The rejection of Claims 1 - 3 and 8 under 35 U.S.C. §103(a) as being unpatentable over Brugger et al. (U.S. Patent No. 6,554,789, "Brugger") is traversed. Both Brugger and Applicants disclose an apparatus which is directed toward solving the same problem, that of providing a blood purification apparatus for removing waste water from blood. It is to be noted, however, that while they are directed to solving the same problem, they each operate in completely different ways. In Applicant's invention, a first measuring means disposed in the arterial blood circuit of the blood circuit measures the blood concentration H_{ta} of the arterial blood circuit; a second measuring means disposed in the venous blood circuit of the blood circuit measures the blood concentration H_{tv} of

the venous blood circuit; and there is additionally a calculating unit which calculates the ratio H_{ta}/H_{tv} of the blood concentrations measured by the first and second measuring means. The calculating unit then calculates the blood concentration ratio as a theoretical value obtained from a designated formula using two parameters, a preset blood flow rate of the blood pump and a blood purifying rate by the blood purifier. It is to be noted that the calculating unit initially calculates two ratios. An evaluation unit then compares the blood concentration ratio as a measurement value with the blood concentration ratio as a theoretical value to determine if they are substantially equal. If the hematocrit value measured by the first measuring means is H_{ta} , and the hematocrit value measured by the second measuring means is H_{tv} , the calculating unit calculates a measured ratio H_{ta} / H_{tv} , and if the preset blood flow rate of the pump is Q_b and the water removal rate of the ultrafiltration pump is Q_{uf} , then the theoretical ratio H_{ta} / H_{tv} is obtained from the following relationship:

$$H_{ta} / H_{tv} = 1 - (Q_{uf} \text{ (preset value)} / Q_b \text{ (preset value)}).$$

The calculating unit calculates the measured and theoretical value ratios using the above relationship. The evaluation unit evaluates whether the two ratios, the measured hematocrit value ratio and the theoretical hematocrit value ratio, are substantially equal by determining whether each of the two ratios is substantially equal to 1; or, whether the difference between the two ratios is close to 0.

Nowhere does Brugger disclose or suggest a calculating unit which first obtains two ratios, a measured ratio value and a theoretical ratio value, and then compares the measured ratio value to

the theoretical ratio value to obtain an evaluation value which is used to evaluate the operation of the blood purification apparatus.

Brugger states (*see* col. 21, lines 24-53) that the blood flow rate, BFR, can be prescribed by an attending physician and input by the operator at the beginning of a treatment session. Thus, in Brugger, the BFR is a fixed value which can be obtained from a reference chart. Brugger also states that an optimal BFR can be obtained from the relationship $BFR = (RFR + UFR) / FF$, where FF is the desired percentage of fluid to be removed from the blood stream through the hemofilter. Nowhere does Brugger disclose or suggest doing what Applicants disclose and claim, that of obtaining two separate ratios which are used by an evaluating unit. For example, Brugger states in col. 22, lines 52-59 that the RFR, the replacement fluid rate, is a fixed number which is prescribed by the attending physician or can be obtained from the relationship $RFR = (BFR * FF) - UFR$. It is to be noted that neither of the resulting figures is a ratio.

Brugger does disclose (*see* col. 24, lines 26 - 34), a device that derives a single blood fluid reduction ratio based upon the difference detected by sensors between the pre-treatment and post-treatment hematocrits, and compares this single ratio with the filtration fraction value (which is not a ratio) to issue a command to the flow restrictor to bring the difference between the readings of the two hematocrits to zero.

Applicants' amended claim 1 recites, in combination, the structure of:

second hematocrit value H_{tv} to obtain the measured ratio value H_{ta}/H_{tv} ; and a preset water removal rate Q_{uf} is divided by a preset blood flow rate Q_b to obtain the theoretical ratio value Q_{uf}/Q_b , as is positively recited in instant Claim 1.

As noted above, Claim 1 positively recites structure which is neither disclosed nor suggested by Brugger and, therefore, is believed to be in condition for allowance. Claims 2, 3 and 8 depend from amended Claim 1 and thus also avoid the Brugger reference.

